Washington Prescription Drug Program's
Preferred Drug List Cost Analysis and Drug Selection Process
(March 27, 2006)

I. Purpose

To establish a consistent methodology for the Uniform Medical Plan (UMP), Health Recovery Services Administration (HRSA) and Labor & Industries (L&I), collectively referred to as "The Agencies" to use when selecting preferred drug(s) within a therapeutic drug class for the Washington State Preferred Drug List (WA PDL).

II. Scope

The methodology described applies to selection of preferred drugs for the drug classes to be included on the WA PDL. Drugs purchased through managed care contracts by the agencies are not included in the cost analysis and thus are not within the scope of this document.

Further, because HRSA dual-eligible clients will no longer use the Washington State PDL after January 1, 2006, HRSA will no longer submit pharmacy utilization data on dual-eligible users for purposes of PDL selection.

III. Background

RCW 70.14.050 authorizes the agencies to collectively determine the preferred drug(s) in a class based on the scientific evidence of efficacy and safety. For drugs with similar efficacy and safety, but with no differences when considered in special populations, the agencies have developed the following process that determines which drug(s) in a class are the lowest net cost to the State of Washington.

IV. Data Quality and Integrity

A. *Determining Status Indicators and Lists of Drug for Inclusion for the Cost Analysis:* The completeness of PDL status assignments and comprehensiveness of drugs listed in the cost analysis in relation to the OSHU list of reviewed drugs will be facilitated by HCA staff prior to development of cost analysis documents Exhibit 1 and Exhibit 2 . The agencies will submit preliminary list of drug for each class in the cost analysis to a third-party actuary conducting the cost analysis. These lists are for preliminary review and development of a pre-report.

B. *Agency Review and Quality Control:* Each agency will have 3-5 business days to review the pre-report for completeness prior to cost analysis modeling. The PDP workgroup will convene to determine changes and achieve consensus if problems with the pre-report are noted.

V. Determining the Average Daily Cost (ADC) in the Cost Analysis

A. Each agency will keep a record of the ADC and the drug "unit" utilization for each drug in a class.

B. Each agency will provide the following data for each National Drug Code (NDC) contained in the drug class to a third-party who will be conducting the cost analysis. The third-party will compute the ADC for each drug in the class.

C. Agencies will submit data for each NDC containing:
   1. NDC
   2. Drug name
   3. Units dispensed
   4. Per unit ingredient price
   5. Per unit federal and state rebates (proprietary and confidential)
   6. Days supplied
   7. Although not needed for the ADC calculation, each agency will also provide the number of scripts written by NDC to estimate administrative costs and co-pay values for the cost model (as described below).

D. Total Net Cost by NDC is computed as Units multiplied by (Per Unit Ingredient Price minus Per Unit Rebates).

E. Total Net Cost by candidate PDL drug is computed as the sum of total net costs by NDC for all NDCs for that PDL drug.

F. Total Days Supplied by candidate PDL drug is computed as the sum of Days Supplied by NDC for all NDCs for that PDL drug.

G. ADC for each candidate PDL drug is computed as Total Net Cost divided by total days supplied.
   1. Prices used for ADC modeling will rely upon the most current data available for each agency (e.g., HRSA prices are updated on a weekly basis).
   2. Utilization information will be based on the last two complete quarters prior to the P&T committee meeting for PDL drugs in new drug class reviews. All subsequent PDL drug class reviews will use the most recently available four complete quarters of data for updates.
   3. Although historical drug utilization data may not always reflect future trends due to price changes, new drug entries to the market and changes in the mix of patients using the drugs, historical information is still the best predictor of future utilization when appropriate actuarial and demographic adjustments are made to the data as required.
   4. Based on historical trends in a drug class estimates will be made for unit cost and rebates for the new generic.
   5. Utilization data for a new generic will use the associated brand's utilization as a proxy for the generic equivalent in PDL selection and potential net savings calculations.
   6. Utilization data will be used in the recommendation process for two basic purposes: First, to model relative shares of individual NDC demand within each drug (e.g. the use of 5mg tabs rather than 20mg tabs of a particular medication). Second, the data will provide an initial basis to estimate savings to the State under various scenarios.

H. HRSA's average daily cost calculations for brand and certain generic drugs include:

1. State and federal rebate amounts paid for the drug(s);
2. For averaging purposes rebates for ADC calculations will be based on the last full 4 complete quarters excluding quarters with a zero rebate amount;
3. A Maximum Allowable Cost (MAC) which may be set for generic and brand drug(s). MAC means the maximum amount that the HRSA pays for a specific dosage form and strength of a multiple-source drug product.
4. The following principles will guide HRSA's ranking of a drug that has a MAC and Automated Maximum Allowable Cost (AMAC), State Maximum Allowable Cost (SMAC), or Federal Upper Limit (FUL).
    a. Generics with or without a MAC will be included in Exhibit 1 and 2 when it will encourage equally effective and less costly utilization;
    b. Brand name drugs with a MAC will be included in Exhibit 1 but will not be included in the PDL selection when it will adversely affect the MAC program by increasing the number of MAC waivers.
    c. HRSA's Division of Medicaid Management (DMM) pharmacy staff will announce future PDL classes to HRSA and establish drug status codes (prepared 3 to 5 business days prior to the cost analysis) for Division of Business and Finance (DBF) pharmacy staff one week before the relevant of the PDL selection in order to allow them to research and set state MAC prices where possible. All agencies to review relevant data no more than 5 business days following the P&T.

I. HRSA, UMP, and L&I will send their respective average daily cost information to an agreed upon third-party to maintain contractually required unit pricing confidentiality for analysis.

VI. Determining the Lowest Net Cost to the State

A. The third-party will model administrative Prior Authorization (PA) costs, co-payments (where applicable), substitution and intra-agency pricing differentials for each drug, rebates and discounts. The administrative cost assumptions and methodology are as follows:
    1. For HRSA and L&I, PA administrative costs have been estimated as a per PA amount. Estimates are based on analysis performed by HRSA and vendor pricing provided by L&I and are annually reviewed for cost modeling. Using actual PA volumes and prescription counts for the last complete two quarters (excluding quarters with zero invoices) provided by HRSA, the third-party correlated the PA frequency to the number of non-preferred scripts (where the number of PA calls was approximately 20% of the number of non-preferred scripts). Administrative costs are estimated as the number of non-preferred scripts multiplied by 20% and then multiplied by the per call charge. No administrative costs are included for UMP.
    2. The co-payment assumptions and methodology is as follows: ADC amounts are reduced by modeled co-payments. For each NDC, UMP provided an assumption of retail or mail order, from which it was assumed that retail drugs were prescribed in a 30-day supply and mail order drugs were prescribed in a 90-day supply. The Total Days Supplied was also provided, which combined with the days prescribed assumption, allowed for the estimation of the number of scripts written. The actual number of scripts written will be included in the data extract sent to the third-party. Generic drugs will be assigned a tier-1 co-pay (10% retail or max/$10 mail) Brand name drugs will be assigned a Tier-2 co-pay (30% or max retail/$40). Co-payment rules applied to each by tier and by retail/mail

order status. The maximum retail co-pay applies when the ADC for generic drugs exceeds $25 (the maximum co-pay of $75 shall be applied to that drug) and when the ADC for brand name drugs exceeds $8.35 (the maximum co-pay of $75 shall be applied to that drug). For Exhibit 1, all brands will be listed as tier 2 and generics listed as tier 1. For Exhibit 2 preferred brand drugs will be listed as tier 2 and non-preferred brands as tier 3 and generics are listed as tier 1.

3. These UMP co-payments will be updated annually.
4. No co-payment reductions were applied to HRSA or L&I calculations.
5. The substitution and intra-agency pricing differential impacts are as follows: For each PDL scenario, those non-preferred drugs that shift to preferred drugs are assumed to do so in proportion to the relative historical utilization of preferred drugs separately for each agency. For HRSA, the percentage of non-preferred drugs assumed to shift to preferred drugs in the savings estimate is based on recent historical levels of preferred drug utilization in the four classes with such history.
6. Substitution for UMP assumes no movement of non-preferred tier one products.
7. Shift assumption may be appropriate to a drug in a proposed PDL class. Agencies will communicate to the third-party their shifting assumptions and those assumptions will be noted in the Exhibits 1 and 2. Intra-agency pricing differentials are considered in the model as drugs in each class are ranked according to the composite average cost for all three agencies combined. This composite ADC uses historical utilization by agency as weights in this computation. Shift analysis will not be used after first PDL selection.

B. The third-party will incorporate these impacts into the ADC to construct an adjusted or net cost ADC for each drug, for each agency. The assumptions and methodology for the adjustment is as follows: The model considers the co-payment adjusted UMP expenses as part of the initial ranking of drugs by class. Administrative costs and substitution rates are considered as part of the savings estimates associated with each PDL scenario by drug class.

C. The third-party will, for each drug class and agency, rank order the ADC for each drug using a weighting relative to the lowest cost drug in a class, again assuring that federal and supplemental rebates are not disclosed. Formula for cost weighting:

Relative Weight (RW) = ADC for a drug / ADC lowest cost drug

D. The results will be arrayed from lowest cost to highest cost subject to the following categorical criteria. Within each therapeutic class, each drug will have a PDL eligibility status defined as one of the following five options:

1. Required for inclusion on the preferred drug list. In most cases this situation is the direct result of a P&T Committee decision (e.g. Lipitor®). It can also result from linkage to other contractual arrangements that make it financially impractical to offer any PDL that excludes the drug (e.g. Imitrex®).
2. Eligible for PDL inclusion. Generics and non-S-MAC brands are generally eligible for PDL inclusion (e.g. lovastatin).
3. Branded generics subject to MAC will be investigated and may not be eligible for PDL depending upon requested price waivers (e.g. Oramorph).

4. Excluded Drugs. Drugs identified by the P&T Committee as being excluded from eligibility for the PDL (e.g. SOMA®). These drugs are expected to have a very selective PA and minimal utilization.
5. P&T Committee selected drugs for specific medical conditions. Similar to Status 1 drugs in that the P&T Committee has directed their inclusion. However, these drugs differ in the model because they address a specific medical condition (e.g. Pravachol®). Therefore, the model assumes their inclusion in the PDL but excludes them from any utilization shifting assumptions as part of the savings estimates.

E. This status identifier (numbered 1-5) will be provided by HRSA. It is included in Exhibit 1 for each drug, which ranks drugs by status and by the all agency combined ADC. The results will be displayed in a format similar to the example below (See Exhibit 1 below).

Exhibit 1: Average Daily Costs (ADC) Rankings

Status	Reviewed Drug Class Name	Days Supply*	Days Supply*	Days Supply*		Relative Daily Cost - Net of Co-pays
	Drugs	HRSA	UMP	L&I	Combined	Combined
1	DRUG A	XX,XXX	XX,XXX	XX	YYY,YYY	**1.00**
2	DRUG B	XX,XXX	XX,XXX	XXX	YYY,YYY	Z.ZZ
3	DRUG C	XX,XXX	XXX	X	YY,YYY	Z.ZZ
4	DRUG D	XX	XXX	X	Y,YYY	Z.ZZ
5	DRUG E	XX	XXX	XXX	YYY	Z.ZZ
6	DRUG F	XX	XXX	XXX	YYY	Z.ZZ

* Exclusive of dispensing fees and pharmacy charges; inclusive of federal and state rebates. The ADC calculations include UMP co-payments.

VII. Decision Methodology to Choose Preferred Drugs in a Class

A. While having a single preferred drug in a class will usually result in the lowest net cost to the state, other issues related to agency business needs, clinical and P&T Committee requests, WAC's and RCW may require increasing the number of drugs in a preferred class.

B. Agency staff recognizes that these constraints, clinical information and common sense will require that adjustments be made on a drug by drug basis. The following presents the framework for the final determination. All medications on the PDL must:
1. Be among the categories of medications that have been reviewed by the Oregon Health & Sciences University Drug Effectiveness Review Project that Washington participates in.
2. Be ranked consistent with any direction given by the Washington State P & T Committee.
3. Exclude brands with generics that have an MAC for the calculations of ADC.

C. New Generic Selections: new generics may enter the market following a PDL drug selection. PDL selection of these generics may require consideration of preferred status due to a reduced unit cost compared to the preferred brand. The new generic should be assessed using the ADC model.

1. If the relative ADC is less than the most expensive preferred status 2 drug, the new generic will not be subject to interchange for a more expensive brand drug.
2. New generics can only be considered if 1) there are known prices, and 2) coincides with a regular drug class cycle for PDL consideration

D. For all drugs within a class that meet the above initial selection requirements the agency staff shall use the tabular data described above and two summary exhibits created by the third-party to assist in the decision process. Those exhibits are as follows:
   1. Exhibit 1 will display the ranking of medications using the RW- ADC price of each medication and the historical utilization for that medication. In situations where new drugs or other changes will impact future utilization those shall be noted and any adjustments documented. In situations were the P & T Committee has made specific recommendations for specific drug(s), they will be added to the top of the list.
   2. Exhibit 2 will display the results of a savings impact analysis by conducting a savings impact analysis using the adjusted ADCs with offsets for administrative costs. Exhibit 2 shows the agency savings, administrative costs and net savings to the state by adding an additional drug in order from the lowest to the highest net cost generic. Subtracting the agency administrative costs from the gross agency savings results in net agency savings. Combining each agency determines net state savings. The drug(s) resulting in the highest net state savings is moved forward for PDL Selection.

E. In situations where new drugs or other changes will impact future utilization they shall be noted and any adjustments documented based on brand-equivalent utilization. (The third-party shall report saving impacts, again assuring unit cost confidentiality.)

F. Initial and updated PDL selection process for use of Exhibits 1 and 2 will have their own section process.
   1. The relative net state saving model (Exhibit 2) may contain inappropriate shifting assumptions once the market shifts have occurred following the initial PDL selection. For subsequent selections the net Average Daily Cost model (Exhibit 1) will likely be sensitive to significant pricing or rebate changes. Therefore selection should rely more on relative net ADC (Exhibit 1) rather than net savings to the state model (Exhibit 2).
   2. Following initial selection and each PDL selection thereafter, the relative ADC will be reviewed for changes to competitive pricing of non-preferred drugs. If an existing non-preferred drug is not significantly different in relative net ADC order, or does not have a relative net ADC significantly different than the lowest relative net weight status 2 drug, then the preferred list shall not change. Exhibit 2 will not be used to determine a change to PDL status unless there is movement in the relative net ADC modeling.
   3. However, after a P&T recommendation, if a non-preferred or preferred drug are significantly different in relative net ADC rank order (i.e., becomes less than or greater than the highest relative net ADC status 2 preferred drugs) Exhibits 1 and 2 should be reviewed and consideration of new preferred or non-preferred selection be made.

Exhibit 2: Savings Relative to Increasing Access to Generic/Brand and Switching

Drug	SAVINGS						
	State	Gross Savings			Net Savings		
	WA	HRSA	UMP	L&I	HRSA	UMP	L&I
Drug A	XX,XXX	XX,XXX	YYY	ZZZ	XX,XXX	YYY	ZZZ
Drug B	XX,XXX	XX,XXX	YY	ZZZ	XX,XXX	YY	ZZZ
Drug C	X,XXX	XXX	Y	Z	XXX	Y	Z
Drug D	XX	XXX	YY	Z	XXX	YY	Z

***** Savings assume the difference between shifting a percentage non-preferred drugs to preferred

G. Agency staff deliberations will include reviews of:
   1. The data presented.
   2. The methodologies and assumptions used.
   3. Buying access assumptions (e.g. % brand/generic).
   4. Consistency with DUR/P&T/Clinical requirements.

H. Agency staff shall make Preferred Drug recommendations to agency heads using information from these deliberations to determine the lowest net cost to the State.

I. Agency heads shall determine the preferred drug(s) in a category based on the PDL agency staff analysis and recommendations. All Preferred Drug determinations shall be reviewed at least annually by the P & T Committee.